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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,498	05/15/2001	John E. Sims	0317-US	8629

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,498

Applicant(s)

SIMS ET AL.

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-58 is/are pending in the application.
- 4a) Of the above claim(s) 40-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24,25,27,28,30,31,34,35,39 and 44 is/are allowed.
- 6) ☒ Claim(s) 21-23,26,29,32,33,36-38,45-48 and 50-58 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Receipt of Applicant's amendment and arguments, filed on 06 June 2003 in Paper No.16, is acknowledged. Claim 21 has been amended. Claims 45-58 have been added. Thus claims 21-58 are pending and under consideration.
2. The following previous rejection are withdrawn in light of Applicants amendments filed in Paper No.16, 06/06/03:
 - (I) The rejection of claims 21, 23, 25, 26, 28, 29 31, 32, 35-38 made under 35 U.S.C. 112, first paragraph, for not being enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO: 13. Dr. John E. Sims, in his Declaration filed under 37 C.F.R § 1.132 by on 06 June 2003 in Paper NO:15, states that the arginine-12 IL-1 epsilon (SEQ ID NO:13) exhibits activities similar to those of Examples III and VI of the instant invention.
 - (II) The rejection of claims 21-23, 26, 29, 32, 36-37, 38 made under 35 U.S.C. 112, first paragraph for not providing an enabling disclosure for an isolated nucleic acid encoding a fragment or a soluble fragment of SEQ ID NO:8 or 13, wherein said fragment is active in IKIB or p38 MAP kinase phosphorylation or in cell surface expression of ICAM-1, is withdrawn, because Applicants arguments pertaining to this rejection were deemed persuasive. Specifically, Applicants' arguments that in the art of molecular biology the level of the ordinary skill is high and knowledge of sophisticated techniques and method are presumed; that only routine experimentation are necessary to make and test the claimed invention, since instant claims recite an operable activity, are found persuasive. Furthermore, Applicants argument that there is nothing in the law

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that requires that specification identifies specific fragments that retain activity, only that the skilled artisan is able to practice the claimed invention without undue experimentation, is also found persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim numbering:

4. Applicants point out that there appears to be an error in the numbering of the claims. However, upon reviewing the claims carefully, the Examiner finds no error in claim numbering. Claims 1-20 were originally filed in the instant Application. Claims 1-20 were canceled and new claims 21-43 were added in the preliminary amendment filed on 22 May 2001 in Paper NO:5. Claims 21-35, 38-39 were amended and new claim 44 was added in the amendment filed on 12 November 2002 in Paper NO:11. Claim 21 was amended and new claims 45-58 were added in the amendment filed on 06 June 2003 in Paper NO:16. The amendment filed on 06 June 2003 in Paper NO:16, indicates that claims 40-43 have been previously canceled, however, there is no record of said cancellation. Therefore, claims 21-58 are pending. Claims 40-43 stand withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim Objection:

5. Claim 49 is objected to because of the following informalities:

5a. Claim 49, in lines 3-4 recites"....., wherein the polypeptide has an amino terminus selected from the group consisting of amino acids 1 through 5, and carboxy terminus is selected from the group consisting of amino acids 154 through 158.", however, it is

suggested to recite the appropriate SEQ ID NO: at the end of the claim, because it is unclear where the recited amino acids are from.

Maintenance of Previous Rejections:

6a. Claims 21-23, 26, 29, 32, 36-37, 38 stand rejected and new claims 45-48, 50-58 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description for the fragment recited in claims 21-23, 36, 37 and new claims 45 and 50, as was set forth in the office action mailed on 02 July 2002, in Paper NO:9, pages 4-6 and reiterated in the office action mailed on 06 February 2003 in paper NO:12, pages 4-6.

Applicants argue that the IL-1 family is well characterized, therefore, the skilled artisan would know which residues are important for activity. Applicants submit Exhibits 1-3 to support this argument.

This argument is fully considered but is not deemed persuasive. The Exhibits submitted by Applicants have also been considered. The members of the IL-1 family have diverse biological activities, therefore, the fact that the structure of this family of proteins is well characterized, does not impart activities common to all of the members. With respect to claims reciting "fragments", instant specification fails to disclose the structure of the claimed fragment. Although instant claims recite operable activity, the claims do not recite structural limitation which correlates to said activity. The issue here is whether the skilled artisan can visualize the structure of the claimed fragment.

Furthermore, the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court held that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or

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physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

New claims 50, 54 and 58 which are drawn to an isolated nucleic encoding a polypeptide that is at least 80% identical to SEQ ID NO:8, and an isolated polypeptide that is at least 80% identical to SEQ ID NO:8, however, the written description in this case only discloses the nucleic acids of nucleotide sequences which encode the polypeptide of SEQ ID NO: 8, and isolated polypeptide comprising the amino acid of SEQ ID NO:8, and therefore the written description is not commensurate in scope with these claims as they are drawn to an isolated nucleic acid molecule comprising a nucleotide sequence that encodes a polypeptide that is at least 80% identical to SEQ ID NO:8, said polypeptide having the recited activities. The skilled artisan would not be able to visualize the structure of the claimed invention. Furthermore, the courts have held, that if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. The fact pattern of the instant case is similar to the latter scenario, because, the members of the IL-1 family have diverse

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biological activities, therefore, the fact that the structure of this family of proteins is well characterized, does not impart activities common to all of the members. Thus, instant specification does not set forth a structural/functional correlation that may be definitive of a genus.

Therefore, Applicants fail to provide written description for claims that recite fragments or percent identity of the polypeptide of the instant invention, which retain the recited activities. As a result, it does not appear that the inventors were in possession of an isolated nucleic acid encoding a fragment or a soluble fragment of SEQ ID NO:8 or 13, which retains the recited activities or an isolated nucleic acid encoding a polypeptide that is at least 80% identical to SEQ ID NO:8, or an isolated polypeptide that is at least 80% identical to SEQ ID NO:8.

6b. Claim 33 stands rejected under 35 U.S.C. 112, first paragraph, because, instant specification does not provide enablement for an isolated polypeptide comprising the amino acid set forth in SEQ ID NO:6. Instant specification does not provide an activity for the polypeptide of SEQ ID NO:6 and Applicants argument that it can be used as a research tool or to raise antibodies is not persuasive. One of ordinary skill in the art would not know how to use the polypeptide of SEQ ID NO: 6, because applicants do not disclose any activities for it. Using the polypeptide of SEQ ID NO:6 as a research tool or to raise antibodies,, because, a compound to be used as a scientific tool where what is being studied is the material itself or to raise antibodies, does not appear to be a specific, substantial and credible utility.

Conclusion

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7. Claims 24, 25, 27, 28, 30, 31, 34, 35, 39 and 44 are allowable.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
18 August 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600